MAY 3 0 2001

K003033

Appendix A

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: May 21, 2001

Applicant: Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Telephone: 858-452-8580
Fax: 858-452-9945
Contact: Louise M. Focht

Device Name:	Staple, Fixation, Bone
Device Trade Name:	Scaphix
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3030
Product Code:	87 JDR
Predicate Device:	Memograph Staple System. (K993714)
Registration Number:	2030506
Owner Operator Number:	9001389

Device Description:

The staple like the predicate device includes various sizes of implants and surgical instrument accessories. The implant allows for repair of a fractured bone.

Indications for Use:

The SCAPHIX Staple is indicated for use in fractures and non-unions of the carpal scaphoid.

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is Memograph Staple System.

Regulatory Class: II
Product Code: 87 JDR

Item	SCAPHIX	*Memograph*
Use	Single use	Single use
Fixation	Staple prongs	Staple prongs
Constraint	Not applicable	Not applicable
Material	Titanium	Nitinol
Sizes	7 sizes, 13, 14, 15, 16, 17, 18, 19	
Indications for use	The SCAPHIX Staple is indicated for use in fractures and non-unions of the carpal scaphoid.	The Memograph Staple is intended for 1)hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2)fixation of proximal tibial metaphysis osteotomy and 3) fixation of soft tissue to bone such as anterior cruciate

Similarities of the Scaphix staple and the Memograph staple system include;

Both devices are intended for single use only;

Both devices are intended for surgical implantation longer than 30 days;

Both devices are used to treat hand bone fragment and osteotomy fixation;

Both devices are made of industry standard materials. No new materials are introduced in either product;

Both devices are comparably sized;

Both devices have similar indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Ms. Louise M. Focht
President
Avanta Orthopaedics, Inc.
9369A Carroll Park Drive
San Diego, California 92121

Re: K003033
Trade/Device Name: SCAPHIX Staple
Regulation Number: 21 CFR § 888.3030
Regulatory Class: II
Product Code: JDR
Dated: March 19, 2001
Received: March 20, 2001

Dear Ms. Focht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003033 .

Device Name: SCAPHIX Staple .

Indications For Use:

The SCAPHIX Staple is intended for use in fractures and non-unions of the carpal scaphoid.

DSMitchell MD for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003033

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR § 801.109) (Optional Format 1-2-96)